



## Is dramatic dietary fat reduction feasible for breast cancer patients in the UK? The results of the WINS(UK) - Stage 1 study

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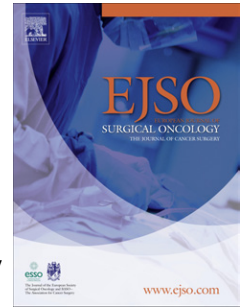
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**Title:**

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**Study design:**

A feasibility study using a randomised controlled, parallel group design to answer the research question:

“Is it feasible for postmenopausal British women, who have received treatment for early stage breast cancer, to halve their reported (baseline) fat intake over 3 months and maintain this reduced intake for a further 21 months, following dietary counselling?”

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**Structured Abstract:**

**Introduction:** The influence of dietary fat on breast tumour growth [1] and, more recently, on treatment outcomes in the large US study [2][3], suggests an important role for dietary advice in the future health of breast cancer patients. The Women's Intervention Nutrition Study (UK) – Stage 1 assessed the feasibility of achieving and maintaining a  $\geq 50\%$  reduction in reported fat intake in postmenopausal, early-stage breast cancer patients in the UK.

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**Method:** This parallel group, randomised controlled trial recruited patients in South-east England between 2000 and 2005. They were randomly allocated to Group 1 ( $n=54$ ), receiving specific dietary counselling to halve their reported fat intake and maintain this low fat intake during 2 years follow-up, or Group 2 ( $n=53$ ), receiving healthy eating advice only. Dietitian-led counselling groups controlled for intervention-associated response set bias [4]. Validated four-day diaries were used to measure intake. Data analysis used Generalised linear model (GLM) for repeated measures and logistic regression.

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**Results:** A significantly greater proportion of women in Group 1 reported a fat intake reduction of  $\geq 50\%$  at 3 months ( $p<.001$ ) and 24 months ( $p<.001$ ) than in Group 2. The size of the effect of active dietary counselling was 37% at 3 months (95% CI: 21 to 54%) and 35% at 24 months (95% CI: 17 to 53%). Mean fat intake was halved at 3 months and 24 months in Group 1 only.

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**Conclusion:** Demonstrating such feasibility is a key step towards exploring further diet's role in secondary prevention of breast cancer.

18

[total word count: 243]

**Key words:**

Diet, dietary fat, breast cancer, dietary counselling.

**Key messages:**

1. Many eligible patients showed an interest in the research and most participated.
2. Breast cancer patients respond positively to the provision of dietary counselling.
3. Group dietary counselling supports patients in the achievement and maintenance of health directed dietary change.
4. This is an important preparatory step, providing support for an intervention study where low fat dietary counselling is researched further as part of adjuvant treatment for breast cancer within the NHS setting.

## Introduction

There is emerging evidence that lifestyle interventions may enhance breast cancer treatment outcomes with a similar effect size to that achieved with drug treatments [5][6]. Unlike other cancers, weight gain is common following treatment for breast cancer and may have a profoundly negative impact on quality of life. Further, post-treatment weight gain may increase the risk of recurrence and decrease survival [7][8][9]. Cohen et al (1993) postulated a threshold effect of dietary fat on breast cancer promotion, based on earlier animal experiments which showed tumour promotion when fat intake exceeded 20% of total energy [1][10].

In postmenopausal breast cancer, dietary fat has been shown to increase endogenous oestrogen production and low fat diets may reduce circulating oestrogens by decreasing intestinal reabsorption [11][12]. Digestion and absorption of dietary fat results in increasing levels of free fatty acids in the blood, transported by serum albumin. Free oestradiol concentrations may be increased due to displacement of oestradiol from the transporter albumin [13].

Trials from Canada [14], the USA [2][15] and Norway [16] indicate that a dramatic reduction in dietary fat intake is feasible, both in women with breast disease and in those at increased risk, but the feasibility of such a diet had not been demonstrated in UK patients with breast cancer.

In this study, entitled WINS(UK) – Stage 1, postmenopausal women were given focussed dietary counselling to investigate whether the achievement of a 50% reduction in reported fat intake was feasible over 3 months and if this reduced intake could be maintained for a further 21 months.

## Methods

One hundred and ninety eligible women previously treated for early breast cancer were randomly assigned to either the intervention group (Group 1) or the non-intervention group (Group 2). Using a standardized programme of dietary counselling and contact time with a registered dietitian, women randomized to Group 1 were given advice and follow-up to reduce their reported dietary fat intake at baseline by  $\geq 50\%$  over a 3 month period. Women randomized to Group 2 were supported to follow a nutritionally adequate eating pattern with no emphasis on dietary fat reduction [17]. In order to provide the appropriate dietary counselling, the dietitian could not be blinded to the group allocation of subjects.

Dietary analysis and reporting was carried out by a trained research assistant. A dietitian's input was only called for if a participant's eating pattern put them at risk of nutrient deficiency and such advice was provided by the senior research dietitian who had no routine role in delivering the dietary counselling.

All participants were offered a total of 2 years follow-up with dietary intake being monitored at baseline, 3, 6, 9, 12, 18 and 24 months, using a validated self-completed 4-day food and drink diary. A validation study was carried out to confirm the suitability of the food and drink diary as a tool for assessing total fat intake in these women. Dietary counseling took place in small groups of up to 10 women. Dietary assessments using Dietplan6 (Forestfield Software Ltd) were conducted by three different research assistants over the study period but standard methodology for estimation of food intake was used to reduce inter-observer variability. Particular use was made of food photographs to define the size and content of a meal as well as descriptive portion size references [18] and a range of qualitative descriptors within Dietplan6 itself to achieve a standardised assessment of intake. Both groups were offered identical follow-up regimens, the variable being the emphasis of the dietary counselling received.

### *Reported versus true intake*

Clotting factor VII was investigated as a potential biomarker for reported fat intake during the early stages of the study, but the correlation was not strong enough to warrant continued measurement [4]. Fasting lipids and weight change were also monitored as proxy indicators of reported intake.

### *Sample Size Calculation*

Sample size calculation was performed on the primary outcome measure i.e. the expected difference in proportions between the groups of those subjects who achieved a  $\geq 50\%$  fat reduction, adjusting for expected drop-out. This calculation predicted that a sample size of 240 women would need to be recruited and followed up over 2 years. Recruitment was slow due to the complexities of screening for eligibility in the context of the NHS. Recruitment was discontinued following an interim analysis of primary outcome data, and a full analysis of the results from 107 women, 86 of whom completed their two years of follow-up, was then conducted.

### *Recruitment*

Patients were screened for eligibility from hospital records at each of the three NHS recruitment sites, and eligible patients were provided with study information and invited to an introductory meeting with the research team. (Figure 1 describes patient recruitment per CONSORT guidance.) Baseline diaries of consenting patients were analysed, and those with a fat consumption of  $< 30\%$  total energy intake were excluded. Group allocation was determined by the University of Southampton Medical Statistics and Computing Department, using a random number generator.

### ***Statistical Analysis***

All statistical analyses were conducted using SPSS. Baseline characteristics of both groups were compared using *t*-tests. Chi squared testing was used to compare the proportions achieving a  $\geq 50\%$  reduction in reported fat intake between groups at 3 months and 24 months. This analysis was supported by 95% confidence intervals of the difference as a result of the emphasis of the dietary counselling received. Further, mean fat intakes were compared between the two groups at baseline, 3 months and 24 months using Generalised Linear Model (GLM) suitable for repeated measures. Logistic regression was applied to the data to estimate the chance of achieving a  $\geq 50\%$  reduction in reported fat intake for intervention group compared with the non-intervention group. Baseline variables were included in the GLM to control for any differences at baseline between the groups. Fasting lipids and weight change were measured as proxy indicators of reported intake and analysed as secondary outcome measures.

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**Results:**

Women who commenced group sessions following randomisation reported higher baseline energy and dietary fat consumption than those who did not (1810 [327] versus 1655 [351] kcal/day, 71.8 [17.3] versus 64.0 [14.6] gm fat/day). Overall, both randomised groups were well matched but Group 2 patients were significantly heavier ( $p<.05$ ) with a larger hip circumference ( $p<.05$ ).

Analysis of primary outcome data showed a significantly greater proportion of women in Group 1 achieved a fat intake reduction of  $\geq 50\%$  both at 3 months ( $p<.001$ ) and at 24 months ( $p<.001$ ). The size of the effect of active dietary counselling was 37% (95%CI:21-54) at 3 months and 35% (95%CI:17-53) at 24 months (Table 1). This was supported by GLM analysis results ( $p<0.001$ ) which adjusted for the baseline variables of age, fat, percentage energy from fat, hip circumference and weight. Mean fat intake at 3 and 24 months within each group remained the same. No significant correlation was observed between reported fat intake and fasting lipid results.

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**[INSERT] Table 1: Baseline, 3 and 24 month results (Primary outcome measures – final analysis)**

Although the dietary counselling did not emphasise weight reduction, both groups lost weight and maintained this loss over 24 months (mean weight loss Group 1 versus Group 2, 3.1kg versus 2.6kg). A corresponding reduction in mean energy intake was also observed in each group (mean energy intake reduction Group 1 versus Group 2, -428kcal versus -277kcal).

Univariate analysis indicated that women in Group 1 were approximately seven times more likely than those in Group 2 to reduce their fat intake by 50% at 3 and 24 months, and more than eight times more likely when adjusting for baseline differences.

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## Discussion:

Dramatic dietary fat reduction has been demonstrated and maintained in post menopausal women following treatment for early breast cancer [3], and the beneficial effects of an adjuvant low fat diet has also been reported in women living in the United States[6]. In order to explore such a relationship further, dietary feasibility has again been demonstrated in a population of breast cancer survivors living in the South East of England, achieving a similar dramatic dietary fat reduction to that achieved by their American counterparts, given specific dietary counselling and support.

The study lacked a true control group as both groups were offered equivalent exposure to the research dietitian over time, thus controlling for intervention associated response set bias. Dietary advice is not part of “usual care” for breast cancer patients and it was considered unethical to withhold healthy eating advice when there was genuine interest in the dietary study. The post-operative prescription of anti-oestrogen drugs has not been examined in the analysis of results but may explain the lack of correlation observed between reported fat intake and the fasting lipid results (data not shown)[7][19][20][21].

### *Potential sources of bias:*

Group 1 was significantly lighter with lower hip measurements than Group 2, suggesting the possibility of differential under-reporting of intake by the heavier women in Group 2[22][23][24]. If this occurred, the true number of those Group 2 participants achieving a  $\geq 50\%$  fat intake reduction should have been less than 5 both at 3 and 24 months, and the size of the effect of the focused dietary counselling to achieve and maintain the halving of fat intake would have been underestimated, not over-estimated. Baseline screening data revealed a clinically over weight study population. Although weight reduction was not a primary aim, participants did experience weight loss in both groups, which may be prognostically favourable [25][26][27]. However, small weight changes such as these could be explained by the impact of the dietary counselling sessions and intake measurement tools increasing awareness of food intake.

Changes in research team personnel during the study may have influenced recruitment rates and introduced inter-observer variability in anthropometric measurements. It was not possible to blind the observer to the group allocation of a participant as measurements were taken during each session. Although the style of dietary counselling may have varied between study dietitians, every effort was made to standardise the topics covered and information given at each education session by using a programme of explicit lesson plans to minimise bias.

The likelihood of selection bias is small as comprehensive screening of patient records was carried out by the same team of researchers at all three recruitment sites. Study information was publicised in out-patient clinics and on surgical wards and quality assurance frameworks established in UK Breast Cancer services are likely to have minimised referral and diagnostic bias. Randomisation of eligible participants was rigorous, and can not explain baseline differences between the two groups.

Women consuming less total energy and fat were less likely to commence group sessions, suggesting response bias. Dietary intake data was not available for those women who declined invitation to the introductory meetings or who subsequently declined to consent to the study (Figure 1). However, of the 1724 invitees, only 48% replied and, of these, 46% declined involvement. All women who completed their eligibility screening with a 4 day food diary were informed of their dietary analysis results and, although they were aware that the study involved potential dietary change, they were unaware of their group allocation. Non-responders may have considered that their diets were appropriate already, making them reluctant to change their intake if randomised into Group 1, and this may impact adversely on the generalizability of the results.

Drop-out was low in those attending an introductory meeting, with only 19% declining to consent. Once group sessions had commenced, subsequent drop out was similarly low(19%), reflecting the active support provided for women throughout follow up and favouring an internally valid study. Subjects who missed a group session were offered “catch-up counselling” to minimise information bias. Intervention-associated response set bias was also controlled for by offering an identical programme of contact time with the research dietitian to both groups.

Breast cancer survivors may not be representative of the general population and may be highly motivated towards lifestyle change in the interests of their future health. This suggestion is supported by the research team’s early exploration of the baseline intakes of participants which revealed significant differences in fruit and vegetable consumption between participants and their age-equivalent counter-parts from the National Diet and Nutrition Survey [28]. This motivation in favour of health directed lifestyle change has been described as “the teachable moment” [29]. Importantly, this offers opportunities to enhance recovery, in line with Department of Health policy initiatives [30] and optimise treatment outcomes by incorporating dietary counselling into the adjuvant treatment regimens for breast cancer patients.

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**Conclusion:**

The study supports the hypothesis that it is feasible for breast cancer patients to achieve at least a halving of their fat intake over 3 months and to maintain this reduced intake for a further 21 months if they are given focused dietary counselling and support. It also confirms the efficacy of goal-specific dietary counselling by a registered dietitian. The small weight loss which was achieved in both groups offers potential benefits to breast cancer survivors as weight gain is associated with poorer prognosis [27][31].

Although the proportion achieving this dramatic fat reduction may have been as little as 21% at 3 months and perhaps only 17% at 24 months, the health impact of 1 in 5 women achieving this goal has important implications in terms of health resourcing. Group dietary counselling offers efficient use of a dietitian's time with the potential for reducing risk of co-morbid health problems, including obesity and cardiovascular disease.

Postmenopausal breast cancer patients living in the South of England can achieve and maintain a large reduction in dietary fat intake when provided with appropriate dietary counselling and support. This study has demonstrated the feasibility of such a programme of dietary intervention and these findings offer additional evidence in favour of a more detailed exploration of diet's role in adjuvant therapy for breast cancer patients in the UK.

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[total word count: 2273]

**What this paper adds:**

- Whilst dramatic dietary fat reduction has been proposed as being of potential importance in breast cancer treatment outcomes, feasibility has not been previously demonstrated in British breast cancer patients.
- Our study suggests that dramatic dietary fat reduction is indeed feasible in women previously treated for early stage, post-menopausal breast cancer following specific dietary counselling provided in small groups.
- Univariate analysis indicated that subjects were at least seven times more likely to achieve a 50% or greater reduction in fat intake when given specific dietary counselling to do so. Subjects who received the specific dietary counselling also showed that such dramatic dietary fat reduction could be maintained over a 2 year period.
- Although the dietary counselling did not emphasise weight reduction, modest weight loss of 2-3kg was observed in both groups over the 2 years of follow-up, an outcome which has been suggested by others to improve prognosis in overweight breast cancer patients.
- The results of WINS(UK) – Stage 1 provide evidence of efficacy and effectiveness for the development of intervention studies to investigate the role of diet in adjuvant treatment of breast cancer.

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### Conflict of interest statement:

All authors have completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare that

- (1) BMP and JMM have received funding, administered by the Winchester and Eastleigh Healthcare NHS Trust, from the World Cancer Research Fund, Winchester Cancer Research Trust and Breast Cancer Research Trust for the submitted work;
- (2) RMR is a trustee of the Winchester Cancer Research Trust and this charity's support for local research may mean that it is considered to have "an interest in the submitted work in the previous 3 years";
- (3) the authors' spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and
- (4) No authors have non-financial interests that may be relevant to the submitted work.

No individual patient data or patient identifiers have been used in this paper. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

### Contributors:

BMP secured the research funding, designed the study, oversaw the creation of data collection tools, monitored data collection for the whole trial and drafted and revised the paper. She is the guarantor. JMM implemented the trial, cleaned and analysed the data and contributed to the drafting of the paper. Dr JM Lawrence, Mrs D David, Mrs Susan Horton and Mrs Judith Stilwell implemented the trial as members of the WINS research team during the conduct of the trial. GY designed the statistical analysis plan, conducted the primary statistical analysis and contributed to the draft paper. RMR initiated the study, instigated the collaborations with recruitment sites, contributed to the study design and revised the draft paper.

### Ethical approval:

Granted in accordance with National Research Ethics Service (formerly COREC) procedures by South and West Local Research Ethics Committee (Ref: 035/A) and South West Surrey Local Research Ethics Committee (Ref: EC32/01). Subjects gave their informed written consent to participate in the study. Consent was not obtained for data sharing but the presented data are anonymised and risk of identifications is low.

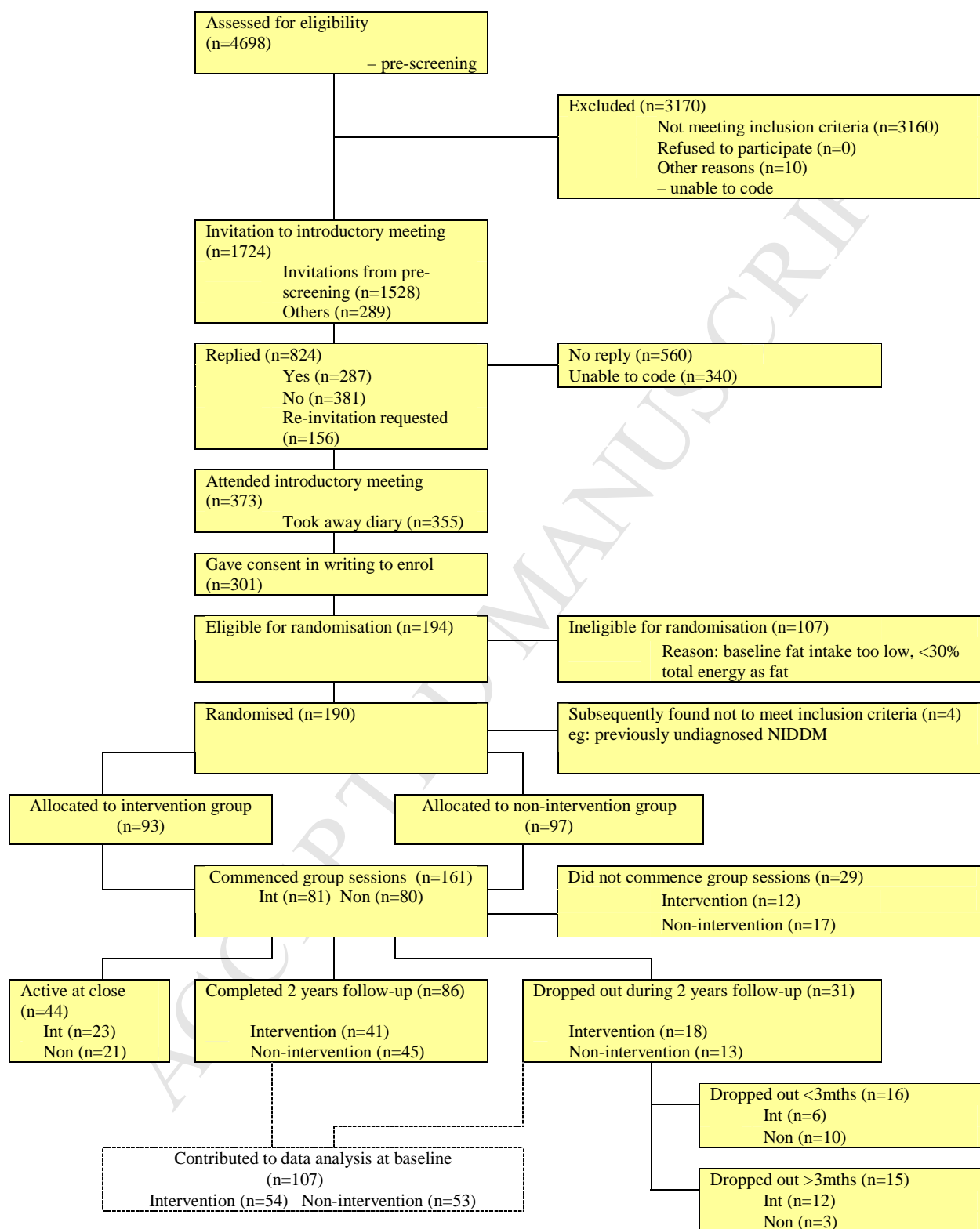
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## Figures and Tables:

Figure 1: CONSORT participant flowchart



**Table 1: Baseline, 3 and 24 month results (Primary outcome measures – final analysis)**

	reported fat intake (g) ‡			proportions achieving ≥50% fat reduction (%)		
Group	Baseline [number]	3 months [number]	24 months [number]	Achieved?	3 months [number]	24 months [number]
<b>1 Intervention</b>	74.9 (21.6) [54]	37.7 (11.5) [50]	40.2 (12.8) [41]	<b>yes</b>	48.0% [24]	46.3% [19]
				<b>no</b>	52.0% [26]	53.7% [22]
<b>2 Non-intervention</b>	71.5 (13.7) [53]	54.0 (16.2) [46]	52.9 (15.3) [45]	<b>yes</b>	10.9% [5]	11.1% [5]
				<b>no</b>	89.1% [41]	88.9% [40]

‡ mean (standard deviation)

Difference in proportions (time)	<i>p</i> value	95% confidence interval of difference
0.48 - 0.11 = 0.37 (at 3 months)	<.001	0.21 – 0.54
0.46 - 0.11 = 0.35 (at 24 months)	<.001	0.17 – 0.54